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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,852	09/20/2000	Guangping Gao	GNVPN.030AUSA	6419

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/665,852

Applicant(s)

GAO ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12, 14, 15, 17-20 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 12, 14 and 15 is/are allowed.
- 6) ☒ Claim(s) 17-20 and 25-27 is/are rejected.
- 7) ☒ Claim(s) 9 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/9/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment and request for continued examination filed 3/9/04. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/9/04 has been entered. Claims 10, 13, 16 and 21-24 have been cancelled. Claims 25-27 have been added. Claims 1, 3, 14 and 17 have been amended. Claims 1-9, 11-12, 14-15, 17-20 and 25-27 are pending in the application.

Information Disclosure Statement

An IDS filed 3/9/04 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Claim Objections

Claims 9 and 11 are objected to because of the following informalities: Claim 9 (a) and (b) recite "chromosomes of the host cell" and in (c) "chromosome of the host cell". For consistency and clarity, it would be remedial to recite in claim 9 parts (a), (b) and (c) "chromosome of the host cell". In claim 11, the article "an" precedes the word "rAAV" whereas the article "a" should precede it. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 25-27 have been added that recite a system for producing recombinant adeno-associated virus. Applicants have indicated that support for claims 25-27 can be found in the specification on page 4, lines 4-15 and 29-30 and on page 6, lines 4-14. These passages teach the following. By provision of only those adenovirus genes, E1A, E1b and E2a, that are essential to the production of rAAV instead of a helper virus, the only virus produced is rAAV as the reformation of wild type helper virus is avoided due to the absence of other adenovirus genes (page 4, line 4-15). The E1a, E1b and E2a gene products are transiently produced and delivered in a transfecting plasmid (page 4, line 29-30). Methods for producing rAAV in the absence of contaminating or wild-type helper may also involve culturing a cell containing a transgene flanked by AAV ITRs, AAV *rep* and *cap* gene sequences and DNA for expression of E1a, E1b and E2a (page 6, line 4-14). Support for recitation of a “system” for producing rAAV has not been in the preceding passages nor has the examiner been able to find literal support in any

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passage in the originally filed of specification for the term “system”. Therefore, the limitation of a “system” is impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17-20 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is vague and indefinite in that the metes and bounds of “E1a (E1b) (E2a) operably linked to a promoter” are unclear. It is unclear if by recitation of E1a, E1b and E2a, it is meant the corresponding gene products or the nucleic acid sequences. In the case of the gene products, it is unclear how the proteins can be linked to DNA promoters.

Claims 25-27 are vague and indefinite in that the metes and bounds of “a system” are unclear. Applicants do not provide a description of “a system” and therefore, it is unclear what constitutes “a system”. While the claims recite that the system comprises a culture of mammalian host cells, it also recites that culturing the cells produces the rAAV. Is the system for producing the rAAV the cell or is it a method of producing the rAAV using the cell or is it a combination of the cell and method steps? It is noted that if the term “system” encompasses both the cell and methods of producing the rAAV using the cell, use of the term in the instant claims directs the claim to non-statutory subject matter (i.e. methods and product claimed together in the same claim).

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Conclusion

Claims 1-8, 12 and 14-15 are allowed.


Claims 17-20 and 25-27 are rejected.

Claims 9 and 11 are objected to for minor informalities.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maria B Marvich, PhD
GERRY LEFFERS
PRIMARY EXAMINER
Examiner
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June 4, 2004